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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,442	02/18/2004	Chengde Wu	TEX4542P0491US	3434

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222 EAST 41ST ST  
NEW YORK, NY 10017

EXAMINER

GRAZIER, NYEEMAH

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 07/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/781,442	<b>Applicant(s)</b> WU ET AL.	
	<b>Examiner</b> Nyeemah Grazier	<b>Art Unit</b> 1626	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 May 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6-15 is/are pending in the application.
- 4a) Of the above claim(s) 7, 12, 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6 and 8-11 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**  
**FINAL REJECTION**

**I. ACTION SUMMARY**

The Amendments to the Claims and Remarks submitted to the Office on May 18, 2006 has been fully considered and will be the basis of the following Action.

Claims 1-5 are canceled. Claims 9-15 have been added. Claims 6, 8-11 and 13 are pending. Claims 7, 12, 14 and 15 are withdrawn.

**II. RESPONSE TO AMENDMENTS**

***A. Election: Response to Election***

As noted in the previous action, the Applicant did not specifically point out the alleged errors in the restriction requirement and therefore the election was treated as an election without traverse. M.P.E.P. § 818.03(a). The requirement is still deemed proper and is therefore made FINAL.

***B. 35 USC §102 Rejection***

Applicant's arguments, see Remarks, filed May 18, 2006, with respect to the various 102 Rejections have been fully considered.

Claims 1 and 3 were rejected under 102(b) as being anticipated by US 6,335,334. The rejection is rendered moot because the claims (1 and 3) have been canceled in the Amendments. The rejection has been **obviated**.

Applicant's arguments concerning the 102(b) rejection of claims 1-3 and 6 and 8 as being anticipated by **J. Med. Chem. 1999, 42, pp. 4485-4499** have been fully considered and are NOT persuasive. Applicants assert that the WU reference is drawn to isoxazolyisulfamoyl compounds and that the instant invention is drawn to thiophene moieties. The rejection is maintained for claims 6 and 8. The rejection is obviated as to claims 1 and 3 because claims 1 and 3 have been canceled. The rejection is maintained because the art of record teaches the compounds. Even though the art of record is drawn to isoxazolyl compounds, the reference anticipates the instant invention because R13 and R14 of instant Formula (II) represents "aryl." The Examiner has sought guidance in the Specification for the term "aryl". On page 11, ll. 23-27 and p. 12, ll. 1-12 "Aryl" "refers to a . . . carbocyclic aromatic group. . . or heteroaromatic. . . such as . . . isoxazolyl." The rejection is **maintained**.

Applicant's arguments concerning the 102(b) rejection of claims 1-3 and 6 and 8 as being anticipated by **WO 98/13366** have been fully considered and are NOT persuasive. The rejection is maintained for claims 6 and 8. The rejection is obviated as to claims 1 and 3 because claims 1 and 3 have been canceled. The rejection is maintained because the art of record teaches the compounds. Even though the art of record is drawn to isoxazolyl compounds, the reference anticipates the instant invention because R13 and R14 of instant Formula (II) represents "aryl." The Examiner has sought guidance in the Specification for the term "aryl". On page 11, ll. 23-27 and p. 12, ll. 1-12 "Aryl" "refers to a . . . carbocyclic aromatic group. . . or heteroaromatic. . . such as . . . isoxazolyl." The rejection is **maintained**.

Applicant's arguments concerning the 102(e) rejection of claims 1 and 3 as being anticipated by **WO 02/28353** have been fully considered and are persuasive because claims 1

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and 3 have been canceled. The rejection has been **obviated**. \*\*\*However, the reference is applicable to claims 6, 8-11 and 13 in light of the Amendments.\*\*\*

***C. Obviousness Type Double Patenting***

Applicant's arguments, see Remarks, filed May 18, 2006, with respect to the provisional obviousness type double patenting rejection has been fully considered. The Applicant request that the rejection is held in abeyance. The rejection is therefore **maintained**.

***D. Objection to the Specification/Claims***

Applicant's arguments, see Remarks, filed May 18, 2006, with respect to objections of the claims and specification has been fully considered. In light of the amended specification and claims, the objection is **withdrawn**.

**III. REJECTIONS**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

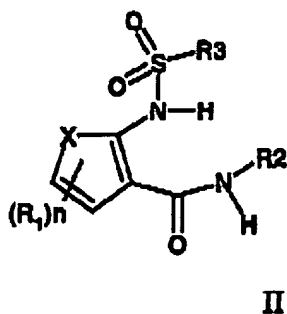
A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 6,8, 9 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by

*Weinstock et al.* WO 02/28353 A2. The instant invention is still anticipated by the *Weinstock et al.* publication. Weinstock et al. teaches compounds of formula (II) as its preferred compounds.

Formula (II) of the Weinstock et al. publication is drawn to:



wherein X is sulfur, R2 is 4-chlorophenyl and wherein R3 is unsubstituted phenyl. The publication discloses: **N-(4-chlorophenyl)-2-[(phenylsulfonyl)amino]-3-thiophenecarboxamide** (See HCAPLUS, Accession No. 2002:275753, RN 409364-73-4, attached). Thus the instant invention is anticipated wherein in the formula (II) E is sulfur, D is oxygen, A is NH and B is SO<sub>2</sub> and R14 is phenyl, Z is NH and R13 is substituted phenyl and R15 and R16 both represent hydrogen.

Applicant's amendment necessitated the new ground of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

#### **IV. Provisional Obviousness-type Double Patenting Rejection**

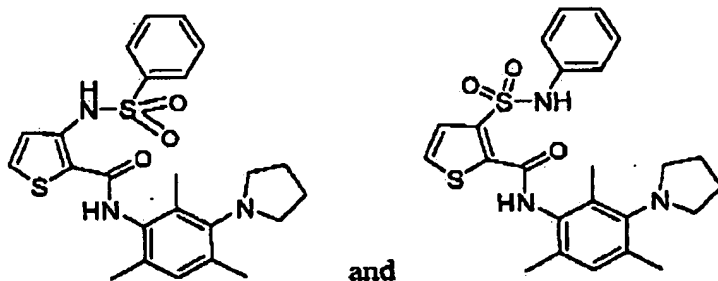
##### ***Provisional Obviousness-Type Double Patenting***

**Claims 11 and 13** are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 6-10 and 12 of copending Application No. 10/924,180 (US 2005/049286A1). The rejection over co-pending application 10/924,180 is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

A rejection based on nonstatutory double patenting is based on a judicially created doctrine grounded in public policy so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). See also M.P.E.P. § 804 (2001).

Obvious-type nonstatutory double patenting rejection is “analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. §103” with the distinction that the double patent rejection is not considered prior art. Id. See also In re Braithwaite, 379 F.2d 594, 154 USPQ 29 (CCPA 1967). Thus, the analysis employed in an obviousness-type double patent rejection is consistent with a §103(a) analysis set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966).

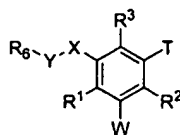
Although the conflicting claims are not identical, they are not patentably distinct from each other because: Claims 11 and 13 recite the compounds and compositions having the following formulae:



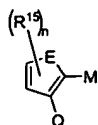
Determining the Scope and Contents of the Co-pending Application

Conflicting claims 1, 3, 6-10 and 12 recite the compounds and compositions of formula

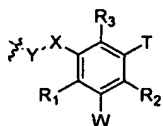
(I)



which include where X is NR<sup>19</sup>, Y is CO, T is NR<sup>4</sup>R<sup>5</sup>, R<sup>4</sup> and R<sup>5</sup> together with the nitrogen to which they are attached form a 5 membered ring, R<sup>6</sup> is aryl, W is H, R<sup>1</sup>, R<sup>2</sup> and R<sup>3</sup> are alkyl (See pp. 93-94, for example, of application 10/924,180). Conflicting claims 8 and 9 recites the compounds of formula (III)



wherein E is sulfur, M or Q is A-B-G-R14 and the other has the structure :



R15 is alkyl, halogen, etc.; n is 0-4; A is NR17 where n is zero; G is NR17 where n is zero; B is SO2; and R14 is aryl. Claim 10 recites the specie: 3-[(phenylsulfonyl)amino]-N-(2,4,6-trimethyl-3-pyrrolidin-1-ylphenyl)thiophene-2-carboxamide.

*Ascertaining the Differences Between the Copending Application and the Instant Claims*

The difference between the instant claims and the copending application is that the claims in the copending application (10/924,180) is a genus of the compound of the invention in the instant application, which is a subgenus.

*Resolving Level of Ordinary Skill in the Pertinent Art*

The pertinent art is cardiovascular drug discovery and generally medicinal chemistry. One of ordinary skill in the pertinent art of medicinal chemistry, specifically, cardiovascular drug discovery would have the motivation to make and use to instant invention because there is motivation to make in the instant compounds in the abovementioned references which teach compounds useful for treatment of conditions associated with Urotensin-II imbalance. The motivation to make claimed compound derives from the expectation that structurally similar compounds are generally expected to have similar properties and have similar utilities. In re Gyurik, 596 F. 2d 1012, 201 USPQ 552 (CCPA 1979).

*Prima Facie Obviousness-The Rational and Motivation (MPEP §2142-2413)*

The prima facie case for obviousness is derived from the structural similarities, specie claims and preferred embodiments. Thus, there is motivation to one skilled in the art to make and use in the instant compounds and compositions with the expectation that they would both have the same pharmacokinetic effect.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application.

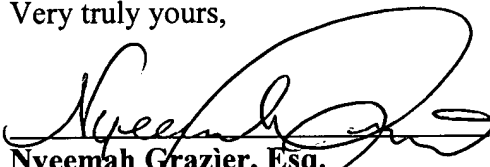
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**V. CONCLUSION**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nyeemah Grazier whose telephone number is (571) 272-8781. The examiner can normally be reached on Monday through Thursday and every other Friday from 8:30 a.m. - 6:00 p.m.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. M<sup>rs</sup>Kane, can be reached on (571) 272 - 0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Very truly yours,



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